DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19, 2014

CenterVue S.p.A.
Mr. Roger Gray
V.P. Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania 10
00153 Rome, Italy

Re: K142047
Trade/Device Name: CenterVue EIDON Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: September 30, 2014
Received: October 2, 2014

Dear Mr. Gray:

This letter corrects our substantially equivalent letter of November 12, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142047

Device Name
CenterVue EIDON

Indications for Use *(Describe)*
The CenterVue EIDON is intended for taking digital images of a human retina without the use of a mydriatic agent.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

centervue

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	CenterVue EIDON Ophthalmoscope
Type of 510(k) submission:	Traditional
Date of Submission:	24 July 2014 (summary revised on 18 September 2014)
Manufacturer:	CenterVue S.p.A. via San Marco 9h 35129 Padova Italy
510(k) Owner:	CenterVue S.p.A. via San Marco 9h 35129 Padova Italy
Phone: **Fax:**	+39 049 7396 147 +39 049 7396 148
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	MYC
FDA Regulation Number:	886.1570
FDA Classification Name:	Ophthalmoscope
Classification Panel:	Ophthalmic
Common Name:	Ophthalmoscope
FDA Classification:	Class II
FDA Identification:	An ophthalmoscope is an AC-powered or battery-powered device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous) and the retina of the eye.
Indications for Use/Intended Use:	The CenterVue EIDON is intended for taking digital images of a human retina without the use of a mydriatic agent.

Device Description:
The CenterVue EIDON scanning ophthalmoscope operates as a standalone unit, running a dedicated software application, intended for prescription use only, and includes:

1. Optical head, including a removable lens cap;
2. Patient head-rest, including removable front-rest;
3. Patient chin rest;
4. Base, including touch-screen device (tablet with magnetic holder and USB cable), USB joystick and an external power supply.

EIDON uses infrared and visible light to obtain colored confocal digital images of a human retina without a mydriatic agent.

The CenterVue EIDON device operates on the following principles:

a) An illumination system consisting of infrared (IR) LEDs (850nm, 940nm), a white LED, a blue LED and a green LED illuminates the patient eye with the following functionality:
   - The IR LED with a centroid wavelength of 850 nm allows the capture of IR photos. The patient retina is uniformly illuminated by a line in a horizontal direction. Along the optical path there is an oscillating mirror which scans the line in order to illuminate the retina with a field of view of 60°.
   - Two IR Leds with a centroid wavelength of 940 nm are seen from the eye in a free viewing system. The two LEDs are equally shifted with respect to the machine optical axis. The LEDS are switched on during all exams in order to enable pupil tracking.
   - The white and blue LEDs allow the capture of color photos. The retina is uniformly illuminated by a line in a horizontal direction. Along the optical path there is an oscillating mirror which scans the line in order to illuminate the retina with a field of view of 60°.
   - The green LED is used as fixation target.

b) An imaging system collects back-reflected light from the retina and creates a high resolution image. A focusing lens is included in the imaging path to achieve optimal retinal focusing on a CMOS camera having a resolution of 14 megapixels.

c) An anterior segment alignment system is included, using two cameras and the two IR LEDs: the LEDs illuminate the anterior segment by diffusion, whereas the cameras allow a stereoscopic reconstruction of the pupil's position to be obtained with respect to the instrument front lens.

The EIDON device interacts with the patient by directing infrared, white, blue and green wavelength illumination into the patient's eye. The chin-rest and head-rest are the only parts of the device that contact the patient. The chin-rest includes a patient proximity sensor and is motorized for height adjustment.

Bench tests
The CenterVue EIDON device has been tested and found to be in conformance with IEC 60601-1:2005 and IEC 60601-1-2:2007. In addition, the device meets the requirements of ISO 10940:2009, ISO 15004-1:2006, and ISO 15004-2:2007.

Performance data:

Performance item	Requirements	Test results
Sensor resolution	14 megapixels (4608 x 3288)	4608 x 3288
Resolution on retina	60 pixel / deg	59.7 pixel / deg
Optical resolution	15 microns at the center	15.1 microns at the center
Field of view	60° (H) x 55° (V)	60.0° x 55.1°
Pixel pitch	4.9 microns max	4.79 microns
Range of focus	-12 D to +15D	-12 D to +15D
Minimum pupil size	3 mm	3 mm

Comparison with predicate devices:
The predicate devices selected for comparison with the CenterVue EIDON Ophthalmoscope are:

Predicate Device 1:.....EasyScan
510(k) Sponsor: .....i-Optics B.V.
510(k) Number: K111988
Clearance Date: .....28 October 2011
FDA Product Code: .....MYC
Classification Name: .....Scanning Laser Ophthalmoscope
Regulation No:.....886.1570

Predicate Device 2:.....Digital Retinography system (DRS)
510(k) Sponsor: .....CenterVue S.p.A.
510(k) Number: K101935
Clearance Date: .....27 October 2010
FDA Product Code: .....HKI
Classification Name: .....Ophthalmic Camera
Regulation No:.....886.1120

The Subject Device and the Predicate Devices share many identical or similar properties and features. Differences include:

- Field of view
- Imaging principle
- Fixation target
- Working distance
- Sensor size
- Minimum pupil size

None of these differences have any significant effect on safety or effectiveness of the Subject Device.

Conclusion:
Based on the information contained within this submission, it is concluded that the CenterVue EIDON Ophthalmoscope is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.